REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested.

Claims 2-6, 15, 17, 18 and 21-27 are currently pending and have been examined on the merits.

Turning now to merits of the Office Action, Applicant acknowledges the Examiner's statement that the previous rejection under 35 U.S.C. § 102(b) has been withdrawn. *See* OFFICE ACTION at 6.

However, the Examiner continues to reject the claims under 35 U.S.C. § 103(a). In particular,

(i) claims 2-3, 5, 15, 17 and 21-26 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over DiGeronimo (United States Patent No. 4,494,357 – hereinafter "the '357 patent") in view of Kodera et al (United States Patent No. 4,366,125 – hereinafter "the '125 patent");[1]

(ii) claim 4 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the '357 patent in view of the '125 patent and further

[1] This rejection under 35 U.S.C. § 103(a) was never made in the previous Office Action as the earlier obviousness rejection did not include the '125 patent. The Examiner has baldly stated that "Applicant's amendment necessitated the new ground(s) of rejection . . . ." However, Applicant's claims always involved the use of hydrogen peroxide and UV light. Moreover, Applicants amendments principally related to amendments concerning the application of air and not the hydrogen peroxide or UV light aspects of the claims. Therefore, the Examiner's use of the '125 patent to show the synergistic effect of hydrogen peroxide and UV was not necessitated by Applicant's amendment. Accordingly, making the subject Office Action final was improper. The Examiner is therefore respectfully requested to withdraw finality of the present Office Action.

in view of Loliger et al. (United States Patent No. 3,692,468 – hereinafter "the '468 patent");

(iii) claim 6 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the '357 patent in view of the '125 patent and further in view of Lagunas-Solare et al. (United States Patent No. 5,364,645 – hereinafter "the '645 patent"); and

(iv) claims 18 and 27 been rejected under 35 U.S.C. § 103(a) as being unpatentable over the '357 patent in view of the '125 patent and further in view of Castberg et al. (United States Patent No. 5,744,094 – hereinafter "the '094 patent").

Each of these rejections is respectfully traversed.

The Manual of Patent Examining Procedure requires that the Examiner adhere to the following tenets of patent law when applying 35 U.S.C. § 103:

(1) "[t]he claimed invention must be considered as a whole;"

(2) "[t]he references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;"

(3) "[t]he references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and "

(4) "[r]easonable expectation of success is the standard with which obviousness is determined."

M.P.E.P. § 2141, at 2100-120. The Examiner has not followed any of these patent law tenets when making each of the four rejections under 35 U.S.C. § 103(a) set forth above.

I. THE COMBINATION OF THE '357 PATENT WITH THE '125 PATENT

Each of the Examiner's obviousness rejections utilize the '357 patent as the primary reference and the '125 patent as the secondary reference.

The Examiner Has Failed to Consider the Claimed Invention As a Whole

Contrary to the Examiner's sweeping statements (*see, e.g.,* OFFICE ACTION at 2-3), the '357 patent does not teach or suggest a method or apparatus for sterilizing a packaging sheet material (or rendering microorganisms present on the surface of packaging sheet material non-viable) by utilizing hydrogen peroxide treatment, air **and** UV radiation. At best, the '357 patent discloses a sterilization process that first subjects the packaging material to ultrasonic vibrations through a liquid medium, wherein the liquid cannot be hydrogen peroxide as it must be free of chemical biocide, next air knives are used for drying the material and thereafter the packaging material is subjected to a source of ultraviolet light. *See* '357 PATENT at Fig. 2. The '357 patent also discloses, separately and in the context of comparative techniques, that either hydrogen peroxide can be used alone (in other words without air and UV radiation) or hydrogen peroxide can be used with hot air treatment (and still without UV radiation). *See* '357 PATENT at Cols. 2-4.

Despite the clear teaching away from using a chemical biocide such as hydrogen peroxide as the liquid medium for the ultrasonic vibration step of the '357 patent, the Examiner has indicated that it would have been obvious to use hydrogen peroxide as the liquid medium in view of the '125 patent which allegedly shows "the importance of the synergistic effect produced by the combination of hydrogen peroxide and UV." *See* OFFICE ACTION at 3-4.

Nevertheless, the combination of the '357 patent and '125 patent still does not permit one of ordinary skill in the art to arrive at Applicant's claimed invention, since none of these references teach or suggest the use of air **to remove a substantial amount of hydrogen peroxide solution on the surface while retaining a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms** present on the packaging material.

The '125 patent perceives a need to apply hydrogen peroxide without removing any, or at least not a substantial amount of, hydrogen peroxide prior to subjecting the packaging material to UV radiation. Applicant's discovery, as discussed in the specification, is contrary to the understandings and expectation of the art, because Applicant has discovered that hydrogen peroxide, when present on the surface of the packaging material, shields the microorganisms from the UV light. Therefore, as Applicant has discovered, when the shielding layer is removed and only a trace or residual amount of hydrogen peroxide is present by being absorbed by or located adjacent to any microorganisms, then the synergism between the UV light and hydrogen peroxide present in or adjacent to the microorganism is much more effective. Moreover, the removal of the shielding layer of hydrogen peroxide allows, if desired, the advantage of using concentrations of hydrogen peroxide which are higher than the maximum levels thought to be utilizable by the prior art.

Accordingly, when Applicant's claimed invention is considered as a whole, it would not have been obvious to those of skill in the art. The combined teachings of the '357 patent and the '125 patent thus do not render the claims of the present application unpatentable.

The Examiner has Failed to Consider the References as a Whole

A prior at reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *See W.L. Gore & Assocs., inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). The Examiner states that the '357 patent "does not teach way from using hydrogen peroxide[.]" OFFICE ACTION at 7. While the '357 patent uses hydrogen peroxide (alone or in combination with hot air, but not with UV radiation) in comparative tests showing the effects of such treatments on bacteria survival, the '357 patent leads the skilled artisan away from using hydrogen peroxide as the liquid medium in the method and apparatus of the '357 patent invention and as depicted in Figure 2 of the '357 patent. Therefore, the '357 patent teaches away from using the combination of hydrogen peroxide, air and UV radiation (as well as this three-part combination in the order recited).

In light of this clear teaching away, the references considered as a whole do not, as they cannot, suggest the desirability and thus the obviousness of making the combination. *See In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Accordingly, the claims of the present application are not unpatentable over the cited references

The Examiner Has Engaged in the Impermissible Use of Hindsight Vision

The Examiner's rejection is necessarily based on improper hindsight since none of the art teaches or suggests the use of air **to remove a substantial amount of hydrogen peroxide solution on the surface while retaining a residual or trace quantity of hydrogen peroxide absorbed by or located adjacent to any microorganisms** present on the packaging material. Additionally, absent

impermissible hindsight, the skilled artisan would not have been motivated to use hydrogen peroxide as the liquid medium in the invention disclosed in the '357 patent (Figure 2) which involves the use of air knives after the liquid bath/ultrasonic treatment and then UV radiation.

Therefore, at the time Applicant's invention was made, one of ordinary skill in the art would not have found the claimed invention to have been obvious over the '357 patent in view of the '125 patent.

The References Do Not Show that There Was a Reasonable Expectation of Obtaining Successful Results

As discussed above, the '125 patent perceives a need to apply hydrogen peroxide without removing any, or at least not a substantial amount of, hydrogen peroxide prior to subjecting the packaging material to UV radiation. Accordingly, prior to Applicant's invention, one of ordinary skill in the art would not have had a reasonable expectation of obtaining the successful sterilization results disclosed by the present application when a substantial amount of the hydrogen peroxide is removed from the packaging material before UV radiation is applied.

Accordingly, Applicant's claimed invention would not have been obvious under the proper standards of 35 U.S.C. § 103(a).

II. THE COMBINATION OF THE '357 AND '125 PATENTS WITH A TERTIARY REFERENCE

The Examiner has rejected some of the claims over the '357 patent in view of the '125 patent and further in view of a tertiary reference – either the '468 patent, the '645 patent, or the '094 patent. None of these references, however, remedy the series deficiencies of the combination of the '357 patent in view of the '125 patent as discussed above.

Thus, the combinations of references which utilize a tertiary reference also do not render the claims of the present application unpatentable.

III. CONCLUSION

Since none of the combinations of references teach or suggest Applicant's claimed invention, withdrawal of each of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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